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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,144	06/20/2001	Jurgen Kleinschmidt	03528.0050.CNUS01	6869

27194 7590 12/19/2003  
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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/886,144

Applicant(s)

KLEINSCHMIDT ET AL.

Examiner

Ulrike Winkler

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on December 3, 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: \_\_\_\_\_.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☒ The drawing correction filed on October 3, 2003 is a) ☒ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The Amendment filed October 3, 2003 in response to the Office Action of June 3, 2003 has been entered. Claim 6 has been canceled in the amendment of October 3, 2003. Claims 1-5 and 7-9 are pending.

The rejection of claims 1-5 and 7-9 under 35 U.S.C. 103(a) as being unpatentable over Shimada et al. (WO96/29349) and Wistuba et al. (Journal of Virology, Sept. 1995) and further in view of Harlow (Antibodies, a laboratory manual, 1988) **is maintained** for reasons of record.

Applicant's arguments have been fully considered but fail to persuade. In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicants amendment to claim 1 limiting the elution range does not overcome the rejection as the elution ranges overlap between the prior art and the instant invention. The Office maintains the position that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to utilize affinity purification methods as taught Shimada et al. for the purpose of purifying AAV and applying the antibody as taught by Wistuba et al. to purify AAV-2. One having ordinary skill in the art would have been motivated to do this in order to purify commercial level quantities of infectious virus AAV-2 suitable for therapeutic

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purposes. One having ordinary skill in the art would have reasonable expectation of success utilizing the antibody as taught by Wistuba et al. for the purpose of purification as taught by Shimada et al. because the antibody is directed to the CAP protein. AAV-2 is a parvovirus that affects humans and is the virus construct most often used in attempts to transfer genes of interest into human cell lines. It would have been obvious to one of ordinary skill in the art at the time the invention was made optimize the affinity chromatography conditions following the standard art known procedures (Harlow et al.), this includes the choice of solid support and the method of eluting the antigen which is directly dependent on the specific antibody used. Elution conditions must be custom tailored because each antibody will have a different affinity/avidity for the antigen and therefore the optimum conditions must be experimentally established. One having ordinary skill in the art would have been motivated to package the required components into a kit for the sake of conveniently providing the reagents to unskilled personnel. Therefore, the instant invention is obvious over Shimada et al. and Wistuba et al. and further in view of Harlow.

### ***Conclusion***


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294, please note after February 2004 the telephone number will change to 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The official fax phone number for the organization where this application or proceeding is assigned is 703-872-9306; for informal communications please use 703-746-3162, please note after February 2004 the fax phone number will change to 571-273-0912

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
ULRIKE WINKLER, PH.D.  
PATENT EXAMINER

12/16/03